REMARKS

Regarding the amendments to the claims:

The amendments to the claims 2, 3, 11, and 25 are directed to provide a more distinct characterizing definition of the nature of the composite material made possible by the present invention, namely in that droplets of a water-in-oil emulsion, said droplets having a controlled distribution of droplet size, are provided in certain aspects of the invention. The term "inclusions" has been deleted from the claim as it is believed to be prolix in light of the amendments to claims 2 and 25.

The amendments to claim 4, 5 improve the form of the claim from a grammatical standpoint.

Regarding the entry of new claims to the application:

In this paper the applicant presents new "product-by-process" claims, viz., claims 28 – 41, in the application.

Regarding the continued rejections under 35 U.S.C. §103(a) in view of US 6,190,591 B1 to Lengerich, Dev. Food. Scie., 1992 to Saleeb, and US 5,290,547 to Bilbrey:

In the prior Advisory Action dated 25.July.2002, the Office remarked that the rejections of record were maintained as "no new unrebutted arguments have been presented". The Applicants respectfully maintain their traversal of these continuing grounds of rejection based on the Lengerich, Saleeb and Bilbrey references. The Applicants also maintain that the newly presented "product-by-process" claims are also inventive, and should be allowed as currently presented.

The Examiner maintains the position that it would have been obvious to one of appropriate skill in the art given the general teaching Lengerich to look further for specific teachings in the prior art to find what can be used at liquid active components. Allegedly, such further specific teachings are provided by the Saleeb and Bilbrey references. The applicants strongly disagree.

In order to properly maintain this grounds of rejection, it is required that the Office show that there is a requisite teaching or motivation to combine prior art references which would lead to the claimed invention. Evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved; see Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 37 USPQ2d 1626, 1630 (Fed. Cir. 1996); Para-Ordinance Mfg. v. SGS Imports Intern., Inc., 37 USPQ2d 1237, 1240 (Fed. Cir. 1995). Often however "the suggestion more often comes from the teachings of the pertinent references," see In re Rouffet, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998). It is required however that such a showing must be clear and particular. See, e.g., C.R. Bard v. M3 Systems Inc.48 USPQ2d 1225 at 1232. (Fed. Cir. 1998).

With regard to evaluating obviousness under 35 USC §103(a), it is impermissible however to combine prior art references without evidence or suggestion, teaching or motivation in the prior art, and use the inventor's disclosure cannot be used as piece together the prior art in order to defeat the patentability of the claims. See Interconnect Planning Corp. v. Feil 227 USPQ2d 543, 547 (Fed. Cir. 1985).

With regard to the continuing grounds of rejection maintained by the Office, the Applicants respectfully disagree with the Office as to what the primary reference relied upon, *viz.* Lengerich, actually teaches. At best, Lengerich actually teaches only a continuous process for producing active controlled-release, discrete, solid particles embedded in a matrix material (Lengerich col. 4, lines 59-63). Lengerich's materials contemplate the use of a plasticized matrix material, into which is incorporated an "encapsulant". This "encapsulant" is the active component which is embedded within the plasticized matrix in a continuous process; this "encapsulant" is thereby incorporated as discrete, solid particles within the matrix component (Lengerich, col. 7, lines 20-24). With regard to the delivery of this active component from within Lengerich's composition, Lengerich clearly points out that a hydrophobic agent can be used to slow down the release rate of the encapsulant from within the plasticizable matrix (Lengerich, col. 8, lines 38-4). Further additional components which are used to delay or prevent a fast release of the encapsulant from the matrix include those having a high water-binding capacity such that they "... may bind water which penetrates the particles, or prevent the water from dissolving the matrix, thereby preventing or delaying the release of the encapsulant from

the matrix." (Lengerich col. 8, lines 62-65). At best then, it is clear that Lengerich teaches that his mechanism for the delivery of his active component ("encapsulant") contemplates the use of specific materials which control the dissolution rate of his plasticizable matrix.

Lengerich mentions also that film-building or film-forming substances can be used to coat his encapsulants prior to incorporation into his plasticizable matrix (Lengerich, col. 13, line 62-col. 14, line 24). Such is very clear from Lengerich when he notes that his encapsulate is pre-coated with a film-building material or a coating material by a process " . . . in conventional manner such as by spraying or enrobing using conventional coating equipment." (Lengerich, col. 16, lines 22-25). It is clear then that Lengerich contemplates that his coated encapsulants are those based on solid materials which are provided with a liquid coating, well prior to their incorporation into any subsequent matrix.

However, *nowhere within the four corners* of the Lengerich reference is there a recitation or even a suggestion of the utility of first forming an aqueous, liquid oil-in-water emulsion which is ultimately used to form a dispersed phase of droplets containing the active ingredient wherein these droplets are of a controlled particle size of small droplets (preferably also of a reasonably narrow range) within a hydrophilic matrix. There is no recitation, nor even the remotest suggestion in the Lengerich reference of the utility of providing such an oil-in-water emulsion as a feed material to an extrusion/mixing process, whereby at the conclusion of the extrusion/mixing process a controlled particle size of small droplets (inclusions) of the active ingredient are provided within the hydrophilic polymer matrix. *Nowhere* in the Lengerich reference is there a description of a process whereby a pre-prepared, oil-in-water emulsion would be used by one of skill in the art as a feedstock to an extrusion/mixing process. Accordingly, absent such a specific teaching, there is also no suggestion or teaching of the utility of such aqueous emulsions in such a mixing/extrusion process.

It is significant to point out that this failure on the part of Lengerich is *not* to be easily overlooked as indeed, it is fair to state that one of appropriate skill in the art seeking within the Lengerich reference for useful technical teaching would not be oblivious to the fact that Lengerich fails to teach or suggest the formation of such oil-in-water emulsions or the likely utility of such oil-in-water emulsions with Lengerich's matrix of materials. In the present application, Lengerich fails to teach or suggest the use of aqueous oil-in-water emulsions as a

feedstock useful with his matrices and indeed, logically "teaches away" from the use of aqueous materials, which would be expected to detract from his controlled release properties. The Office is not permitted to overlook such a "teaching away" in the prior art but must consider the reference as a whole.

"The relevant portions of a reference include not only those teachings which would suggest particular aspects of an invention to one having ordinary skill in the art, but also those teachings which would lead such a person away from the claimed invention. [...] The board's approach amounts, in substance, to nothing more than a hindsight 'reconstruction' of the claimed invention by relying on isolated teachings of the prior art without considering the overall context within which those teachings are presented. Without the benefit of appellant's disclosure, a person having ordinary skill in the art would not know what portions of the disclosure of the reference to consider and what portions to disregard as irrelevant."
In re Mercier 185 USPQ 774, 778 (CCPA, 1975)

A skilled artisan, carefully reading the Lengerich patent would understand that a key factor of the success of Lengerich's compositions is the delivery is based on aqueous solubility of Lengerich's matrix, the same careful reader would understand why Lengerich would reasonably avoid the use of feedstocks or materials which included a significant proportion of water, as adding such water would defeat the controlled release characteristics which Lengerich provides by his matrix. As noted above, Lengerich needs to control the aqueous dissolution characteristics for his compositions for them to work properly; thus, adding in any component which is rich in water, such as an aqueous oil-in-water matrix would be expected to undermine the technical characteristics of Lengerich's compositions. This shortcoming clearly undermines the necessary link to the secondary references of Bilbrey and Saleeb relied upon by the Office.

Additionally there is nothing in the Lengerich reference which is can be seen to be useful in teaching or reasonably suggesting how an extruded material can be produced, which extruded material includes droplets of a liquid active ingredient as inclusion in the extruded matrix material, and wherein these droplets are desirably present as very fine and relatively uniformly distributed droplets. Such a matrix containing very fine and relatively uniformly distributed droplets of an active material provide specific technical benefits, --- which only the current Applicants provide in their invention ---, which are not available from the prior art. Such technical benefits are not to be overlooked. For example, the Applicants illustrate in their Figures 2 and 3 certain differences in the morphology and in the technical behavior of an

extrudate formed according to a conventional prior art process (Fig.2) as opposed to an extrudate formed according to the present invention's process (Fig.3). As is elucidated at page 10, at the paragraph beginning at line 13 the present inventive process provides means for providing "inclusions" of a very small, and controllable process size. Such provides important technical benefits such are discussed with reference to Figure 3. As is also elucidated, the present inventors have also surprisingly found that providing "inclusions" of a very small, and controllable process size can be achieved to a great degree, independently of the specific apparatus, and that in contrast to the prior art, that ".. inclusion sizes below 2 mm, preferably below 1 mm are obtained." (Applicant's specification, page 10, lines 18 – 20.) Nothing in the prior art describes such a process, or such an extrudate, as the present applicants now claim. Nothing in the prior art clearly teaches or suggests that by forming an aqueous oil-in-water emulsion containing an active constituent, and then introducing the said aqueous oil-in-water emulsion containing the active constituent could or would result in an extrudate which the present applicants have provided.

It can be fairly stated then that only using a hindsight reconstruction, can one produce the Applicants' claimed invention from the assorted bits-and-pieces gleaned by the Examiner from the primary Lengerich, and the secondary, Saleeb and Bilbrey references and by ignoring the technical limitations of Lengerich's matrices. However, such a hindsight reconstruction is also impermissible under the law. See W.L. Gore & Associates, Inc. v. Garlock, Inc. 220 USPQ 303 (CAFC, 1983); In re Mercier 185 USPQ 774, 778 (CCPA, 1975); In re Geiger 2 USPQ2d 1276 (CAFC, 1987)

The Examiner continues to maintain a rejection based on the combination of the primary and secondary references stating that there is sufficient motivation within the secondary references to combine them with Lengerich. The Examiner points out that in Saleeb, there are discussed reduced oxidation and extended shelf life related to fine emulsion droplets.

The Applicants respectfully disagree with the Examiner's interpretation of the Saleeb reference, and respectfully directs the attention of the Examiner to the passage at page 660, lines 3 through page 661, line 8. It is the Applicants' view that the relevant portion of that specification as indicated relates to orange oils which have been encapsulated in a spray-drying process (page 660, line 8) which are *dried, solid particles* and which are only subsequently

mixed with the dry powder forming the major portion of Saleeb's matrix. For example, Saleeb describes at page 653, at the first full paragraph, his process wherein he unequivocally relates that "... these dry powders with or without flavors are fed automatically to a multi-zone extruder provided by specified die . . . as these components melt, the major component will dissolve in to the minor component, forming a viscous homogenous fluid which enrobes the flavored droplets added with powder, but preferably metered into the middle of the extruder." Thus, it can be clearly seen that Saleeb's techniques are related towards the formation of an extruded blend which has as starting materials, pulvurent flavorants and pulvurent matrix materials. *Nowhere in the four corners* in the Saleeb reference is there a teaching or suggestion of forming an active ingredient in the form of an oil-in-water emulsion and in using these as a feedstock to the extrusion process. The sole use of emulsifiers in Saleeb is recited at page 658, 659 wherein Saleeb discusses the selection of an emulsifier so to optimize the oil droplet distribution within the matrix. However, nothing in the Saleeb reference can be seen to teach or suggest forming an active ingredient in the form of an oil-in-water emulsion. Nothing in the Saleeb reference can be seen to teach or suggest using an active ingredient in the form of an oil-in-water emulsion as a feedstock to the extrusion process. Indeed, Saleeb's addition of an emulsifier to his composition does not form an oil-in-water emulsion, but at best forms an "oil-in-substrate" emulsion, although the "substrate" is a "glass" composition used by Saleeb in his experimental analysis. Even so, Saleeb's oil droplets have a larger average particle size (approx. 4.6 microns), and the distribution of his droplet size favors the formation of larger, not smaller droplets, such as the range 0.01 – 2 microns now claimed by the present Applicants.

Accordingly, it is not seen how the Saleeb reference, with its own inherent shortcomings, can be used to cure the fatal defects of the Lengerich reference discussed above. Neither of these documents satisfies the deficiency of the other. More particularly, neither document discusses the utility or the desirability of first forming their active constituent into an oil-in-water emulsion which can be introduced into the barrel of an extruder/mixer. Neither document teaches or suggests that such an active constituent provided as an oil-in-water emulsion could be extruded to form a product with the type of droplet sizes, or droplet size distribution which only the present Applicant's teach.

The Examiner also continues to rely upon the secondary reference to Bilbrey as ostensibly teaching a method to form oil-in-water emulsion droplets, which however Bilbrey used as a coating material to be applied onto a substrate by spraying. Bilbrey notes that desirably, his droplets have a relatively large size, preferably in the order from about 15-25 microns in diameter which can be achieved by adding a thickening agent soluble in the fragrance oil, especially the use of polyvinyl butyral (Bilbrey, col. 3, lines 10-50). Thereafter, these thickened oils are then combined with an aqueous solution of a water-soluble polymer binder such that the continuous phase is the aqueous solution of the water-soluble polymer binder, within which is a discontinuous phase formed of the thickened fragrance oil (Bilbrey col. 3, line 60-64). Thereafter, this composition is applied to a substrate such as pet litter (Bilbrey, col. 5, line 35-37).

While related to a coating composition, nothing in the Bilbrey reference would suggest to one of appropriate skill in the art of the utility of his compositions in any other manner or for any other use other than what is explicitly recited. This fact, coupled to the complete silence of Lengerich as to the utility of oil-in-water emulsions as a material useful for incorporation into his matrix by extrusion/mixing does not, in the Applicants' view, give rise to an appropriate ground for maintaining the outstanding rejection. Again, only by the impermissible of hindsight, or the use of the Applicants' own specification to teach the invention which is also prohibited, can the benefits of the Applicants' claimed invention be realized. See W.L. Gore & Associates, Inc. v. Garlock, Inc.; In re Mercier, *supra*.

Accordingly, reconsideration of the propriety of the rejections based in view of the combined Lengerich, Saleeb, and Bilbrey references, and their withdrawals is requested.

As pointed out above, the Applicants traverse this rejection, as Saleeb does not describe a water-in-oil emulsion which is added to a matrix material and combined by mixing/extrusion. As has been noted above, Saleeb's recitation of emulsifiers appears to be relevant only insofar as the addition of an emulsifier in Saleeb's melt formed well after his pulvurent feed materials have been supplied to his extruder. Saleeb's emulsifier, which he discusses at pages 658-659 refers only to the addition of an emulsifier to the essential oil which produces a fine emulsion when the flavorant is mixed with the melted substrate during extrusion. However, there is no recitation of the addition of an aqueous oil-in-water emulsion to his matrix material. Such is not the same as

the Applicants' claimed invention, or their discovery of the improved benefits attendant upon the addition of a water-in-oil emulsion to a matrix in a mixing/extrusion operation. It cannot be seen how the Examiner can conclude, as the Examiner recites at page 5-6 of the outstanding Office Action that "... even if Saleeb failed to teach oil-in-water emulsion, which in the Examiner's view is not the case, a non-obviousness of the claimed invention should be shown in view of the combined references a whole. In this case, the encapsulation of oil-in-water microemulsion is taught by Bilbrey. The mere fact that Saleeb lacks the explicit mention of the type of its microemulsion does not necessarily render the claimed invention non-obvious."

The Applicants respectfully, but emphatically disagree with this line of reasoning. The proper test of obviousness is not one of the assemblage of the claimed invention by hindsight, which is impermissible, but what the combined references as a whole would have suggested to one of appropriate skill in the art. However, the Courts have long held that "It is wrong to use the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit. Monday morning quarterbacking is quite improper when resolving the question of non-obviousness in a court of law." Orthopedic Equipment Company, Inc. et al. v. United States 217 USPQ 193 (CAFC, 1983) As discussed thoroughly above, none of the prior art references considered individually teach a process, or a product produced by a process wherein a liquid oil-in-water emulsion is added to a mixing/extrusion step, and subsequently forms a continuous matrix phase having embedded within a discontinuous phase of the oil. Lengerich is wholly silent as the utility of oil-in-water emulsions, and does not provide an appropriate teaching or suggestion for the use of such emulsions in his type of composition. Indeed, Lengerich can properly be said to "teach away" from the use of an aqueous component due to the nature of his matrix, and the need to maintain hydrophobicity in order to ensure controlled release of his "encapsulant". Saleeb fails to demonstrate an oil-in-water emulsion; at best, teaches only the benefits of dispersing his oils within the melted matrix present within his extruder. However, no oil-in-water emulsion is provided by Saleeb. Bilbrey's emulsions are not taught to be useful in any manner other than described by Bilbrey, namely in forming a coating which is deposited onto a substrate. There is no suggestion or motivation either in Bilbrey, or in Lengerich which would suggest the compatibility of the materials in each of these references. Indeed, it can be stated that the

addition of any type of aqueous material would be seen as particularly detrimental to Lengerich's matrices which are particularly controlled or "tailored" to have specific hygroscopic properties to thereby control the release of Lengerich's "encapsulants". There would be an obvious technical prejudice, realized by one of appropriate skill in the art, to add any type of aqueous additive to Lengerich's matrix compositions as such would be expected to diminish or indeed destroy the efficacy of Lengerich's extruded compositions. Of course, such an aqueous composition of the type described by Bilbrey would be viewed as highly detrimental to Lengerich due to the aqueous content of Bilbrey's oil-in-water emulsions. As such, there no motivation to combine these references, but the inherent nature of Lengerich's matrices would induce this skilled practitioner to avoid the inclusion of any aqueous compositions.

In conclusion, the Applicants respectfully request full reconsideration of the outstanding grounds of rejection, particularly in view of the amendments entered to the present claims, as well as in view of the newly presented claims. See In re Eli Lilly Co. 14 USPQ2d 1741 (CAFC, 1990)

Reconsideration of the outstanding grounds of rejection and their withdrawal in view of the foregoing remarks is respectfully requested.

Should the Examiner in charge of this application feel that communication with the Applicants' undersigned representative would advance the prosecution of this application, they are invited to contact the undersigned at the telephone/telefax numbers given below.

Respectfully submitted,

Date: 09 Sept. 2002

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"Marked Up" Copy of the Claims

2. (Twice Amended) A composite material comprising a thermoplastic hydrophilic matrix having dispersed therein droplets of a hydrophobic active ingredient, said droplets having a droplet size in the range of 0.01 – 2 microns. [and a liquid active ingredient dispersed in an oil-in water emulsion, wherein the liquid active ingredient forms inclusions in the matrix of uniformly distributed droplets, with a droplet size of between 0.01 μm to 2μm.]

3. (Amended) A composite material according to claim 2 wherein the droplets [inclusions] have a droplet size of between 0.04 μm and 1 μm.

4. (Twice Amended) A composite material according to claim 2 wherein the [a] load of the active ingredient in the composite material is between 1 to 50% w/w.

5. (Amended) A composite material according to claim 5 wherein the [a] load of the active ingredient in the composite material is between 5 to 15% w/w.

11. (Twice Amended) A method for preparing a composite material comprising:

(a) mixing a liquid active ingredient in a oil-in-water emulsion with a matrix premix comprising a thermoplastic hydrophilic polymer; and

(b) extruding the mixture of (a) to form a composite material characterized in that the composite material comprises a thermoplastic hydrophilic matrix and a hydrophobic liquid active ingredient dispersed as droplets in the said matrix said droplets having a droplet size in the range of 0.01 – 2 microns .

25. (Amended) A protective or controlled release system for an active ingredient comprising a composite material comprising a thermoplastic hydrophilic matrix and a hydrophobic [an] active ingredient dispersed as droplets within the thermoplastic hydrophilic matrix having [in a oil-in-water emulsion wherein the active ingredient forms inclusions of

uniformly distributed droplets with] a droplet size in the range of 0.01 – 2 microns .[of between 0.01 μm to 2 μm in the matrix.]

New claims added:

28. A composite material comprising thermoplastic hydrophilic matrix and a hydrophobic liquid active ingredient dispersed as droplets in the said thermoplastic hydrophobic matrix said droplets having a droplet size in the range of 0.01 – 2 microns produced by a process which includes the steps of:

(a) forming a mixture of a liquid active ingredient in a oil-in-water emulsion with a matrix premix comprising a thermoplastic hydrophilic polymer; and

(b) extruding the mixture of (a) to form a composite material.

29. The composite material according to claim 28 wherein the process including the further step of:

introducing the mixture of (a) into an extruder before extrusion.

30. The composite material according to claim 28 wherein the process includes the further step of:

introducing an oil-in-water emulsion containing the hydrophobic liquid active ingredient into a barrel of an extruder, which barrel contains the matrix premix, and mixing the oil-in-water emulsion with the matrix premix.

31. The composite material according to claim 28 wherein the process includes the further step of:

forming a mixture of a hydrophobic liquid active ingredient in a oil-in-water emulsion, with a matrix premix comprising a thermoplastic hydrophilic polymer wherein the polymeric fraction comprises 50% w/w to 100% w/w of the matrix premix.

32. The composite material according to claim 28 wherein the process includes the further step of:

forming a mixture of a hydrophobic liquid active ingredient in a oil-in-water emulsion with a matrix premix comprising a thermoplastic hydrophilic polymer wherein the oil-in-water emulsion contains 5 to 80% w/w active ingredients, 10 to 90% w/w water, 0.5 to 10% w/w emulsifier, and 0 to 10% w/w additives.

33. The composite material according to claim 28 wherein the process includes the further step of:

forming a mixture of a hydrophobic liquid active ingredient in a oil-in-water emulsion with a matrix premix comprising a thermoplastic hydrophilic polymer wherein the oil-in-water emulsion contains 30 to 60% w/w active ingredients, 15 to 40% w/w water, 0.5 to 10% w/w emulsifier, and 0 to 10% w/w additives.

34. The composite material according to claim 28 wherein the process includes the further step of:

forming a mixture of a hydrophobic liquid active ingredient in a oil-in-water emulsion with a matrix premix comprising a thermoplastic hydrophilic polymer wherein the matrix premix comprises a hydrophilic thermoplastic polymer and an additive.

35. The composite material according to claim 28 wherein the process includes the further step of:

forming a mixture of a hydrophobic liquid active ingredient in a oil-in-water emulsion with a matrix premix comprising a thermoplastic hydrophilic polymer wherein the hydrophilic thermoplastic polymer is selected from the group consisting of native starch, modified starch, thermoplastic starch, polyvinyl alcohol, its copolymers, and polyesters.

36. The composite material according to claim 34 wherein the additive is selected from the group consisting of cross linking agents, plasticizers, antiplasticizers, fillers, and mixtures thereof.

37. The composite material according to claim 28 wherein the process includes the further step of:

forming a mixture of a hydrophobic liquid active ingredient in a oil-in-water emulsion with a matrix premix comprising a thermoplastic hydrophilic polymer wherein the oil-in-water emulsion further comprises an emulsifier and a surfactant.

38. The composite material according to claim 37 wherein the emulsifier is selected from the group consisting of a modified starch, a sucrose or sorbitol ester of a fatty acid, a carbohydrate, a phospholipid, and mixtures thereof.

39. The composite material according to claim 37 wherein the surfactant is selected from the group consisting of a monomolecular surfactant, a polymeric surfactant, and a colloid stabilizer.

40. The composite material according to claim 39 wherein there is also present a co-surfactant.

41. The composite material according to claim 40 wherein the co-surfactant is a primary alcohol or a short chain alkylsulfate.